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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,092	06/15/2005	Robert Petermann	112701-626	9222

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EXAMINER	
DEES, NIKKI H	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
04/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/539,092	PETERMANN ET AL.	
	Examiner	Art Unit	
	Nikki H. Dees	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-11 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed February 10, 2009, has been entered. Claims 1, 2, 5-11, and 13 are currently pending in the application. Claims 3, 4, and 12 have been cancelled. The previous objection to claim 12 is withdrawn in view of the cancellation of claim 12. The previous 112 rejection of claim 5 is withdrawn in view of the amendment to claim 5.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 5-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (6,475,539) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html).

4. DeWille et al. teach a nutritional formula that comprises a protein source, a carbohydrate source, a lipid source, and lactic acid. The formula in its liquid state has a pH of 3.0-4.6 (col. 6 lines 13-47). The solution may be directly acidified. That is, the pH of the solution may be adjusted by the addition of the acid, not fermentation (col. 15 lines 9-34). The nutritional formula may be provided as a ready-to-feed form,

concentrate, or powder (col. 10 lines 26-30). Protein sources taught for use in the invention include whey protein and casein. The whey protein is used as a concentrate or isolate, which, as an essentially undenatured protein, is considered to be intact (col. 11 lines 36-50).

5. Regarding claims 7-9, DeWille et al. teach that the formula is prepared by first forming a protein/carbohydrate/oil mixture that is then acidified with an edible acid (col. 20 lines 1-9).

6. Regarding claims 10 and 11, the statements of intended use for the methods are not considered to patentably distinguish over the prior art. DeWille et al. teach preparing acidified nutritional formula by directly adding lactic acid to the nutritional formula (col. 15 lines 9-34). Further, low pH in foodstuffs is known to inhibit microbial growth (col. 6 lines 8-10).

7. Regarding claim 13, the amount of acid in the invention encompasses the range of percentages as claimed by applicants when calculated on a dry weight basis using claims 1 and 7 of DeWille et al. As DeWille et al. teach lactic acid for use in their invention, and their formula has a pH in the range overlapping the range claimed by Applicant's, it would have been expected that the amount of lactic acid needed to provide a pH as claimed by DeWille et al. would fall within the range claimed by Applicants.

8. DeWille et al. are silent as to their invention comprising L(+) lactic acid and to the formula being an infant formula.

9. Purac teaches the availability of edible L(+) lactic acid solution. The FCC products are indicated to be foodsafe.

10. One of ordinary skill in the art at the time the invention was made, desiring to acidify the invention of DeWille et al. with lactic acid, would have found it obvious to use L(+) lactic acid to provide the acidification. L(+) lactic acid was known in the art for addition to foodstuffs, and lactic acid is specifically taught as an acidulent in the nutritional formula of DeWille et al. Applicant is doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff. Therefore, the combination of DeWille et al. the PURAC products FCC 50, 80 or 88 would have been obvious to one of ordinary skill in the art at the time the invention was made.

11. Regarding the invention of DeWille et al. being an infant formula, one of ordinary skill in the art at the time the invention was made, wishing to provide a complete nutritional product for infants rather than children 13 months and older as taught by DeWille et al. (col. 10 lines 55-59) would have been able to modify the nutritional profile of DeWille et al. in order to provide a nutritional formula that met the nutritional needs of infants. One of ordinary skill, working from the teachings of DeWille et al., would have found it obvious to provide a shelf stable product that met the nutritional needs of infants. These modifications would not have required undue experimentation, and would have been expected to result in an appropriately acidified infant nutritional formula.

12. Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

13. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

14. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

15. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

16. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

17. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding

infants as taught by Schwartz with L (+) – lactic acid as taught by the WHO in order to result in an infant formula with higher acidity for improved digestion.

19. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

20. Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

21. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

22. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

23. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

24. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

25. Purac teaches edible L(+) lactic acid that is in compliance with all major food codices.

26. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) lactic acid as taught by Purac to result in an infant formula with higher acidity for improved digestion. Applicant is utilizing a known compound, L(+) lactic acid, for its intended use as a food acidulent in order to provide the obvious combination of an acidified infant nutritional formula. This combination is further considered to obvious as there would be no undue experimentation required to utilize the L(+) lactic acid where the addition of lactic acid is specifically taught by Schwartz.

27. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

28. Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata (4,212,893) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

29. Takahata teaches an acidified whole milk beverage comprising whole milk and an organic acid (Abstract). Organic acids taught include lactic acid (col. 2 lines 32-36). The final pH of the beverage taught is within the range of 2.5 to 4.5 (col. 2 lines 25-27).

30. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

31. Takahata is silent as to the enantiomeric ratio of lactic acid present in his composition.

32. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized L (+) – lactic acid in the beverage taught by Takahata in order to result in a beverage that may be marketed to the widest possible audience, including infants.

Response to Arguments

34. Applicant's arguments filed February 10, 2009, have been fully considered but they are not persuasive.

35. With regard to the 103 rejection over DeWille in view of PURAC, Applicant argues that the disclosure of product literature from PURAC does not provide specific reason to choose the product as claimed (Remarks, p. 5)

36. DeWille discloses an invention comprising lactic acid, as detailed above. The specific lactic acid for use in the invention is not detailed. The PURAC product is a commercially available L(+)-lactic acid that is taught to be safe for use in foodstuffs. One of ordinary skill, when producing a food formulation requiring lactic acid, would have found it obvious to have selected a known, commercially available, food-safe lactic acid for use in the invention.

37. Applicant further argues the combination does not teach a formula that is safe for infants, as required by the present claims (Remarks, p. 5).

38. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., infant safety) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

39. The rejection of claims 1, 2, 5-11 and 13 over DeWille in view of PURAC meets the limitations of the rejected claims, including the may be modification to suit the nutritional needs of infants. There is no requirement that the combination of DeWille in view of PURAC be proven in the prior art as "safe" as Applicants contend.

40. Applicant continues to argue (Remarks, pp. 5, 6, 7) that WHO fails to teach the use of L(+) lactic acid in formula and WHO teaches away from using L(+).

41. Applicant is directed to the "Evaluation" section of the WHO document, where it is noted that there is no limit of acceptable daily intake of lactic acid by man, other than the teaching against the use of D(-)-lactic acid and DL-lactic acid in infant foods. Lactic acid, to the examiner's knowledge, exists in only 3 forms, D(-)-lactic acid, L(+)-lactic acid, and the racemic mixture, DL-lactic acid. A teaching away from the use of D(-)-lactic acid and DL-lactic acid would have clearly indicated to one of ordinary skill that only the L(+)-lactic acid is suitable for use in infant foods. If, as applicant contends, the teachings of the WHO against DL- and D(-) lactic acids also constitute a teaching against L(+) lactic acid as it is a constituent of DL-lactic acid, Applicants are invited to provide evidence of other forms of lactic acid that might be added to infant foods.

42. The examiner also again directs applicant's attention to the Alm reference, which was cited in the conclusion of the Office Action mailed November 20, 2008, for further evidence in support of the use of L(+) lactic acid in infant nutritional formulas.

Conclusion

43. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nikki H. Dees/
Examiner, Art Unit 1794
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794